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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,865	YE ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-23 are pending in the application and are currently subject to a restriction and election requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1, 2, 20, and 21, drawn to a polypeptide or a fragment thereof, classified, for example, in class 530, subclass 350.

Group II. Claim 3, drawn to an antibody, classified, for example, in class 530, subclass 387.9.

Group III. Claims 4, 5, 8-11, 22, and 23, insofar as the claims are drawn to a nucleic acid molecule encoding a polypeptide or a fragment thereof, a vector comprising said nucleic acid molecule, a host cell containing said vector, and a method for producing the polypeptide encoded by said nucleic acid molecule, wherein said nucleic acid molecule hybridizes to the complement of the polynucleotide sequence set forth in SEQ ID NO: 1 or shares at least 80% homology with the polynucleotide sequence set forth in SEQ ID NO: 1 or SEQ ID NO: 3, classified, for example, in class 536, subclass 23.5, class 435, subclass 320.1, class 435, subclass 325, and class 435, subclass 69.1, respectively.

Group IV. Claim 6, drawn to a gene chip comprising a nucleic acid molecule, classified, for example, in class 435, subclass 287.2.

Group V. Claim 7, insofar as the claim is drawn to a transgenic non-human animal comprising the comprising a nucleic acid molecule, wherein said nucleic acid molecule hybridizes to the complement of the polynucleotide sequence set forth

in SEQ ID NO: 1 or SEQ ID NO: 3, classified, for example, in class 800, subclass 10.

Group VI. Claim 12, drawn to a method for detecting a polypeptide or fragment thereof, classified, for example, in class 435, subclass 7.1.

Group VII. Claim 13, insofar as the claim is drawn to a method for detecting a nucleic acid molecule, wherein said nucleic acid molecule hybridizes to the complement of the polynucleotide sequence set forth in SEQ ID NO: 1 or SEQ ID NO: 3, classified, for example, in class 435, subclass 6.

Group VIII. Claims 14, insofar as the claim is drawn to a method for identifying a modulator of a polypeptide, said method comprising contacting said polypeptide with an agent and determining if said agent has modulated the function or activity of said polypeptide, classified, for example, in class 435, subclass 4.

Group IX. Claims 14 and 15, insofar as the claims are drawn to a method for identifying a modulator of a polypeptide, said method comprising administering to a host cell comprising an expression vector encoding said polypeptide an agent and determining if said agent has modulated the function or activity of said polypeptide, classified, for example, in class 435, subclass 375.

Group X. Claim 16, drawn to a method for identifying an agent that binds a polypeptide, said method comprising contacting said polypeptide with an agent and assaying the resultant mixture to determine if said agent has bound said polypeptide, classified, for example, in class 435, subclass 7.1.

Group XI. Claim 17, drawn to a pharmaceutical composition comprising an agent that binds a polypeptide, classified, for example, in class 530, subclass 387.1.

Group XII. Claim 18, drawn to a method for treating a disease or condition, said method comprising administering to a patient an agent that binds a polypeptide, classified, for example, in class 514, subclass 2.

Group XIII. Claim 19, drawn to a method for identifying a modulator of the expression of a polypeptide, classified, for example, in class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-V and XI are products, whereas the inventions of Groups VI-X, XII, and XIII are processes.

The inventions of Group I and the inventions of Groups VI, VII, IX, X, XII, and XIII are unrelated because the products of Group II are not specifically used or otherwise involved in the processes of Groups VI, VII, IX, X, XII, and XIII.

The inventions of Group II, IV, and V and the inventions of Groups VI-X, XII, and XIII are unrelated because the products of Group II, IV, and V are not specifically used or otherwise involved in the processes of Groups VI-X, XII, and XIII.

The inventions of Group III and the inventions of Groups VI-VIII, X, and XII are unrelated because the products of Group III are not specifically used or otherwise involved in the processes of Groups VI-VIII, X, and XII.

The inventions of Group XI and the inventions of Groups VI-X and XIII are unrelated because the products of Group XI are not specifically used or otherwise involved in the processes of Groups VI-X and XIII.

The inventions of Group I and the inventions of Group VIII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the polypeptide can be used in a materially different process of using that product, such as the process of using the polypeptide as an immunogen to produce an antibody that binds the polypeptide.

The inventions of Groups I and the inventions of Group VIII have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter, and the search performed in examining claims drawn to a product is a different from the search performed in examining claims drawn to a process using that product. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Group I would not suffice to provide adequate information regarding the merit of the claims of Group IX or XIII, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups I and the inventions of Group VIII, an examination of both would constitute a serious burden.

Since the inventions of Groups I and the inventions of Group VIII have been shown to be patentably distinct, and because the examination of both inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

The inventions of Group III and the inventions of Groups IX and XIII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the host cell comprising a polynucleotide encoding a polypeptide can be used in a materially different process of using that product, such as the process of using the host cell to produce the polypeptide.

The inventions of Groups III and the inventions of Groups IX and XIII have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter, and the search performed in examining claims drawn to a product is a different from the search performed in examining claims drawn to a process using that product. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Group III would not suffice to provide adequate information regarding the merit of the claims of Group IX or XIII, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups III and either of the inventions of Groups IX and XIII, an examination of both would constitute a serious burden.

Since the inventions of Groups III and the inventions of Groups IX or XIII have been shown to be patentably distinct, and because the examination of both inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

The inventions of Group XI and the inventions of Group XII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the composition comprising an agent that binds a polypeptide can be used in a materially different process of using that product, such as the process of using agent to purify the polypeptide by affinity chromatography.

The inventions of Groups XI and the inventions of Group XII have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter, and the search performed in examining claims drawn to a product is a different from the search performed in examining claims drawn to a process using that product. Apart from the searching patent databases using the patent classification of the claimed subject matter,

a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Group XI would not suffice to provide adequate information regarding the merit of the claims of Group XII, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups XI and the inventions of Group XII, an examination of both would constitute a serious burden.

Since the inventions of Groups XI and the inventions of Group XII have been shown to be patentably distinct, and because the examination of both inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

The inventions of Groups I-V and XI are patentably distinct for the following reasons:

The inventions of Group I are polypeptides; whereas the inventions of Group II are antibodies, the inventions of Group III are nucleic acid molecules, vectors comprising such nucleic acid molecules, and host cells comprising such nucleic acid molecules, the inventions of Group IV are gene chips, the inventions of Group V are transgenic animals, and the inventions of Group XI are compositions comprising agents that bind a polypeptide.

Polypeptides and polynucleotides are chemically distinct products, since polypeptides are composed of polymers of amino acids, whereas polynucleotides are composed of polymers of nucleotides. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, a polypeptide can be produced by means, other than the recombinant means by which a polynucleotide encoding a polypeptide might be used to produce the polypeptide, since a polypeptide can be produced (or isolated) by biochemical means, including, for example, affinity chromatography. In addition, while the polynucleotide might encode the polypeptide, generally, it can also encode another polypeptide using the information provided by an alternative open reading frame; and furthermore, since a polynucleotide can be used as a probe in hybridization-

based analyses, the information provided by a polynucleotide can be used isolate different polynucleotides encoding polypeptides, which have amino acid sequences that differ from the amino acid sequence encoded by the disclosed polynucleotide. Consequently, the disclosed relationship between a polynucleotide capable of encoding a polypeptide and the polypeptide is not exclusive, since either the claimed polynucleotide or the claimed polypeptide can also be related to other polynucleotides or polypeptides, which are materially and chemically different from the claimed inventions. Therefore, the inventions of Group I and the inventions of Group III are patentably distinct products.

The inventions of Group I and the inventions of Group III have acquired a separate status in the art, as evidenced by their different classifications, and the search performed in examining claims drawn to a polynucleotide is a different from the search performed in examining claims drawn to a polypeptide. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims directed to the inventions of Group I would not suffice to provide adequate information regarding the merit of the claims directed to the inventions of Group III, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Group I and the inventions of Group III, an examination of both would constitute a serious burden. Moreover, because the disclosed relationship between the polynucleotide and the polypeptide encoded by the polynucleotide is not absolute or exclusive of other relationships with different polynucleotides or polypeptides, the search of either group will likely provide information that is relevant to one but not the other; and as such, searching one in addition to the other would be unduly burdensome.

Since the inventions of Group I and the inventions of Group III are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

An antibody, such as an immunoglobulin G (IgG) molecule, typically comprises four polypeptides: two light chains and two heavy chains, each containing constant and variable regions, which interact with one another to form an antigen-binding domain comprised of amino acid residues in each chain. In contrast, the claimed polypeptides are disclosed as consisting of a single polypeptide chain; so the inventions of Group I and the inventions of Group II are structurally distinct from one another. Thus, any relationship between an antibody and a polypeptide to which the antibody binds is codependent upon the structural (i.e., antigenic) information provided by the polypeptide, which is recognized as the antigenic determinant to which the antibody binds, and the selective binding nature of the antigen-binding domain of the antibody. However, a polypeptide comprises multiple antigenic determinants and can thus elicit the production of multiple different antibodies, which recognize and bind structurally distinct portions (i.e., epitopes) of the polypeptide. Furthermore, an antibody is capable of recognizing and binding antigenic determinants that are shared by polypeptides, which are otherwise structurally and/or functionally distinct from the claimed polypeptide to which it binds (e.g., a human protein's mouse homolog, or a different member of a functionally related family of proteins). Consequently, the disclosed relationship between an antibody that binds a polypeptide and the polypeptide is not exclusive, since either the claimed antibody or the claimed polypeptide can also be related to other polypeptides or antibodies, respectively, which are materially and chemically different from the claimed inventions. Therefore, the inventions of Group I and the inventions of Group II are patentably distinct products.

Searching both the inventions of Group I and the inventions of Group II would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. A search of relevant sequence databases using the entire amino acid sequence of the polypeptide as query is necessary for the determination of the novelty and unobviousness of the polypeptide. However, such a search is not necessary, or sufficient to identify antibodies that bind the polypeptide, since antibodies that bind an epitope of the polypeptide may be known, even if the polypeptide is not (e.g., a anti-phosphotyrosine antibody binds a phosphotyrosine epitope, which is shared by numerous different proteins, and which would bind a novel tyrosine phosphorylated polypeptide).

Accordingly, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, having to search the inventions of Group I and the inventions of Group II would constitute a serious burden.

Since the inventions of Group I and the inventions of Group II are patentably distinct and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Group III are nucleic acid molecules, vectors comprising such nucleic acid molecules, and host cells comprising such nucleic acid molecules; whereas the inventions of Group II are antibodies. A polynucleotide is composed of polymers of nucleotides, whereas antibodies are composed of polymers of amino acids. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, the claimed polynucleotide does not encode a polypeptide chain of the claimed antibody; and the claimed antibody cannot be encoded by the claimed polynucleotide. Therefore, the inventions of Group III and the inventions of Group II are patentably distinct products.

Searching both the inventions of Group III and the inventions of Group II would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. Therefore, having to search both the inventions of Group III and the inventions of Group II would constitute a serious burden.

Since the inventions of Group III and the inventions of Group II are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

Any of the inventions of Groups I, II, III, V, and XI and the inventions of Group IV are patentably distinct products. The inventions of Group IV are gene chips or microarrays. The

other products and a microarray are structurally and functionally distinct. A microarray is a device or apparatus comprised of an organic (e.g., cellulose) or inorganic (e.g., silicone) material or composite to which is covalently attached a biological material (e.g., peptide, nucleic acid, or antibody). In contrast, a nucleic acid, for example, is a polymer of nucleotides. Although both the microarray comprises a nucleic acid molecule, the nucleic acid molecule of which such a microarray is comprised is attached to a solid support and "arrayed" together with other nucleic acid molecules in precise manner. Therefore, the search required to examine claims drawn the inventions of Group IV is not the same as, nor coextensive in nature and scope with the search required to examine claims drawn to any of the inventions of Groups I, II, III, V, and XI.

Searching any of the inventions of Groups I, II, III, V, and XI and the inventions of Group IV would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with any other. A search of relevant sequence databases using the entire nucleotide sequence of the nucleic acid molecule, for example, as query is necessary for the determination of the novelty and unobviousness of the nucleic acid molecule, as it is for the determination of the novelty and unobviousness of a microarray comprising such a nucleic acid molecule. However, such a search is not sufficient to identify microarrays comprising the nucleic acid molecule, since the nucleic acid molecule is not necessarily contained arrayed in a microarray. Furthermore, a microarray comprising such a nucleic acid molecule may be known, even if the nucleic acid is not, because microarrays are often configured of a large plurality of often novel nucleic acids. Accordingly, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, having to search any of the inventions of Groups I, II, III, V, and XI and the inventions of Group IV would constitute a serious burden.

Since any of the inventions of Groups I, II, III, V, and XI and the inventions of Group IV are patentably distinct and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

As for any relationship between any of the inventions of Groups I, II, III, IV, and XI and the inventions of Group V, there is none, since, for example, the transgenic animals do not produce any of the other products.

While it might be argued that the transgenic animals and the nucleic acid molecules encoding the proteins, or the proteins are related, animals are living organisms comprised of a multitude of other structurally and functionally unrelated nucleic acid molecules and proteins. As such, the inventions of any of Groups I, II, III, IV, and XI and the inventions of Group V are patentably distinct.

Searching the inventions of any of Groups I, II, III, IV, and XI and the inventions of Group V would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. Therefore, having to search the inventions of any of Groups I, II, III, IV, and XI and the inventions of Group V would constitute a serious burden.

Since the inventions of any of Groups I, II, III, IV, and XI and the inventions of Group V are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Group XI are not structurally or functionally related to the any of the inventions of Groups I, III, IV, or V. The inventions of Group XI are compositions comprising agents that bind a polypeptide; and although the agent could comprise an antibody, the agent is not an antibody, nor does it necessarily comprise an antibody, since, for example, it might be another type of ligand (e.g., a peptide capable of binding the polypeptide).

For this reason, searching the inventions of Group XI and any of the inventions of Groups I, II, III, IV, and V would be unduly burdensome, because the necessary searches are not the same, nor are they coextensive in nature and scope with one another and/or the inventions have acquired a separate status in the arts, as evidenced by their separate classifications and/or art-recognized divergence in subject matter. Therefore, having to search more than one the inventions of Group I, II, III, IV, and V together with the inventions of Group XI would constitute a serious burden.

Since the inventions of Group XI and any of the inventions of Groups I, II, III, IV, and V are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups VI-X, XII, and XIII are unrelated, or are otherwise patentably distinct, each from the other, for the following reasons:

The inventions of Groups VI are methods for detecting a polypeptide; in contrast, the inventions of Group VII are methods for detecting a nucleic acid molecule, the inventions of Groups VIII and IX are methods for identifying a modulator of the activity or function of a polypeptide, the inventions of Groups X are methods for identifying an agent that binds a polypeptide, the inventions of Group XII are methods for treating a disease or condition, and the inventions of Group XIII are method for identifying a modulator of the expression of a polypeptide.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects. See MPEP §§ 806.04 and 808.01. The instant specification does not appear to disclose that the inventions of Group VI, the inventions of Group VII, any of the inventions of Groups VIII and IX, the inventions of Group X, the inventions of Group XII, and the inventions of Group XIII are useable together. Therefore, because the inventions of Group VI, the inventions of Group VII, any of the inventions of Groups VIII and IX, the inventions of Group X, the inventions of Group XII, and the inventions of Group XIII have different purposes, the inventions appear unrelated.

If not unrelated, the inventions of Group VI, the inventions of Group VII, any of the inventions of Groups VIII and IX, the inventions of Group X, the inventions of Group XII, and the inventions of Group XIII are patentably distinct, each from the others, for the following reasons:

Again, the inventions of Group VI, the inventions of Group VII, any of the inventions of Groups VIII and IX, the inventions of Group X, the inventions of Group XII, and the inventions of Group XIII have different purposes or objectives.

In addition, the inventions of Group VI, the inventions of Group VII, any of the inventions of Groups VIII and IX, the inventions of Group X, the inventions of Group XII, and

the inventions of Group XIII are materially different processes comprising different process steps. For example, the inventions of Group VI, which are processes for detecting a polypeptide, comprise contacting a sample with an agent that allows detecting of the polypeptide (e.g., an antibody); in contrast, the inventions of Group VII, which are processes for detecting a nucleic acid molecule, comprise contacting a sample with oligonucleotide. Furthermore, as the inventions of the different groups have different purposes or objectives, they involve the measurement of different endpoints and the establishment of different correlations, and accordingly they necessarily have different criteria for success. For these reasons, the inventions of Group VI, the inventions of Group VII, any of the inventions of Groups VIII and IX, the inventions of Group X, the inventions of Group XII, and the inventions of Group XIII are patentably distinct from the others.

Because the inventions of Group VI, the inventions of Group VII, any of the inventions of Groups VIII and IX, the inventions of Group X, the inventions of Group XII, and the inventions of Group XIII are distinct for these reasons, the search required to examine claims directed to any one of these inventions is not the same, nor is it coextensive with the search required to examine claims directed to any other. Furthermore, the inventions of Group VI, the inventions of Group VII, any of the inventions of Groups VIII and IX, the inventions of Group X, the inventions of Group XII, and the inventions of Group XIII have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter. Because different searches would have to be performed to examine claims directed to the inventions of Group VI, the inventions of Group VII, any of the inventions of Groups VIII and IX, the inventions of Group X, the inventions of Group XII, and the inventions of Group XIII, an examination of more than one would constitute a serious burden.

Since the inventions of Group VI, the inventions of Group VII, any of the inventions of Groups VIII and IX, the inventions of Group X, the inventions of Group XII, and the inventions of Group XIII have been shown to be patentably distinct, each from the others, and because the examination of more than one could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

The inventions of Groups VIII and IX are patentably distinct, since, although both are processes for identifying a modulator of the activity or function of a polypeptide, the inventions of Group VIII comprise contacting the polypeptide with an agent and determining if the agent has modulated its activity or function, whereas the inventions of Group IX comprise contacting a cell comprising a nucleic acid molecule encoding a polypeptide with an agent and determining if the agent has modulated its activity or function. Thus, the processes of Groups VIII and IX are materially different processes comprising different process steps.

Because inventions of Groups VIII and IX are distinct for these reasons, the search required to examine claims directed to one of these inventions is not the same, nor is it coextensive with the search required to examine claims directed to the other. Furthermore, inventions of Groups VIII and IX have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter. Because different searches would have to be performed to examine claims directed to inventions of Groups VIII and IX, an examination of both would constitute a serious burden.

Since inventions of Groups VIII and IX have been shown to be patentably distinct, and because the examination of both could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D., whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
September 19, 2006